

DEPARTMENT OF PUBLIC HEALTH
AND HUMAN SERVICES

CHAPTER 110

FOOD AND DRUG STANDARDS

Subchapter 8

Drinking Water and Ice

37.110.801 DRINKING WATER (1) Any person engaged in the production, packaging, manufacturing or processing of drinking water, culinary bottled water, or water otherwise processed and packaged for human consumption, is subject to the licensing requirements of 50-50-201, MCA, for food manufacturing establishments. Any manufacturing or bottling plant located in a state, territory, or nation other than Montana that prepares water in bottles or other containers for drinking or culinary purposes for sale in Montana must also be licensed by the department.

(2) Each food manufacturing establishment in Montana where water is prepared for sale in bottles or other containers for human consumption and the sources of all such water must be inspected at least once each year by the local health officer, sanitarian or sanitarian-in-training employed by or contracted with the local board of health having jurisdiction. A copy of each inspection must be submitted to the department within 30 days after the inspection occurs.

(3) Each food manufacturing establishment in Montana where water is prepared for sale in bottles or other containers for human consumption must:

(a) obtain its water from a community public water system approved by the water quality division of the department of environmental quality, or, if water is obtained from a separate or independent system, that system must comply with the statutes governing public water supplies, 75-6-101 et seq., MCA, the rules governing public water supplies, ARM 17.38.201 et seq., and the rule governing plans for public water supplies or wastewater systems, ARM 17.38.101.

(b) maintain sampling records demonstrating compliance with the bacteriologic, chemical and radiologic sampling requirements specified in (6)(b) of this rule for at least 12 months after the date of sampling.

(4) The operation of all food manufacturing establishments involved in producing, packaging, manufacturing, or processing drinking or bottled water and the products marketed must comply with these rules and with the Montana Food, Drug and Cosmetic Act, 50-31-101 et seq., MCA; the food manufacturing establishment rules, ARM 37.110.301 et seq.; the federal standards regarding food labeling, 21 CFR 101; the federal quality standards for foods with no identity standards, 21 CFR 103; the federal standards for processing and bottling of bottled drinking water, 21 CFR 129; and the Fair Packaging and Labeling Act, 15 USC 1451 et seq.

(5) Every food manufacturing establishment desiring to sell, market or distribute bottled water in Montana, whether located in Montana or not, must apply for a license on a form provided by the department, which must be signed by the owner or the owner's legal representative, and must submit the fee required by 50-50-206, MCA. Such fee must be payable to the department and the application must be postmarked no later than midnight on December 31 of each year. Submission of a renewal application and fee after this time will require the food manufacturing establishment to submit the late fee required by 50-50-206, MCA. The license year is January 1 through December 31.

(6) In addition to the fee, the late fee, if applicable, and the application form identified in (5) above, the food manufacturing establishment must submit the following to the department for review:

(a) A certification affidavit from the state or local health officer, sanitarian or sanitarian-in-training employed by or contracted with the local board of health having jurisdiction, affirming that the establishment meets the requirements of 21 CFR 103 and 129;

(b) If the source water is not mineral water, copies of the most recent inorganic, volatile organic, organic chemical and radiological analyses of the establishments water showing compliance of the source water with the maximum contaminant levels for regulated water systems as required by 40 CFR 141; or a certification affidavit from the state or local health officer, sanitarian, or sanitarian-in-training employed by or contracted with the local board of health having jurisdiction, affirming that the water source complies with these standards;

(c) Test results for pesticides and synthetic organic chemicals, if the department determines such tests are necessary or if random testing has shown there is or may be contaminants present at levels which may adversely affect public health;

(d) A copy, photocopy, or printer's proof of each label for each product to be marketed and for each size to be marketed;

(e) A description of the source of the water, water treatment used, all substances added to the water, and any other documentation required by the department to verify that labels and terminology used on the labeling conform with applicable law; and

(f) For products labeled "mineral water" or for a label containing the term "mineral water", copies of the results of laboratory testing of mineral content and total dissolved solids (TDS) of the product, obtained during the 12 months preceding the license year from an agency approved to test drinking water by the department or another public health agency.

(7)(a) The department hereby adopts by reference:

(i) ARM 37.110.301 et seq., setting standards for food manufacturing establishments;

(ii) ARM 37.110.201 et seq., setting standards for public water supplies;

(iii) ARM 17.38.101, governing plans for public water supplies;

(iv) 21 CFR 101, setting food labeling standards;

(v) 21 CFR 103, setting quality standards for foods with no identity standards;

(vi) 21 CFR 129, setting standards for processing and bottling bottled drinking water;

(vii) 40 CFR 141, containing maximum contaminant levels for drinking water, and

(viii) 15 USC 1451 et seq., containing federal law on packaging and labeling.

(b) Copies of these statutes and rules may be obtained, upon payment of copying costs, from the Department of Public Health and Human Services, Food and Consumer Safety Section, 1400 Broadway, P.O. Box 202951, Helena, Montana 59620-2951. (History: Sec. 50-31-104, 50-31-201 and 50-50-103, MCA; IMP, Sec. 50-31-104, 50-31-201 and 50-50-103, MCA; NEW, 1994 MAR p. 2832, Eff. 10/28/94; AMD, 1995 MAR p. 368, Eff. 3/17/95; TRANS, from DHES, 2001 MAR p. 2423.)

37.110.802 ICE (1) This rule applies only to ice that is intended for human consumption and is sold in packaged form or in bulk form for food, drink or culinary purposes. This rule does not apply to persons, hotels, restaurants, inns, caterers, food service contractors, or theaters that manufacture or furnish ice solely to or for their customers in a manner that is incidental to the production, sale or dispensing of other goods and services.

(2) Natural ice that is cut from water on a stream, creek, river, lake, pond, or other body of surface water may not be used as ice for human consumption.

(3) Except as provided in (1) above, any person who manufactures, transports, distributes, sells or provides ice, with or without charge, to the public must obtain a food manufacturing license and must comply with these rules and with the statutes governing food manufacturing establishments, 50-50-101 et seq., MCA; the rules governing food manufacturing establishments, ARM 37.110.301, et seq.; and the rules governing public water systems, ARM 17.38.201 et seq.

(4) Ice plants must be operated in a clean and sanitary manner. The room in which ice production occurs may not be used for any purposes other than ice or food production and the storage and refrigeration of ice or food.

(5) Ice production facilities shall meet the provisions of 21 CFR 110, which provides standards for current good manufacturing practice in manufacturing, packing, or holding human food.

(6) Ice produced and packaged for sale to the public must be labeled in accordance with the Montana Food, Drug and Cosmetic Act, Title 50, chapter 31, MCA, and in accordance with 21 CFR 101, which establishes federal food labeling standards, and must display legible labeling including, but not limited to, the identity of the product, the net weight or contents of the package, and the name and place of business of the manufacturer, packer, distributor, seller, or provider.

(7) Packaged ice transportation, hauling vehicles, and bulk containers, including display or storage freezers, are regarded as a part of the licensed premises and are subject to review or inspection by the department or the local health officer, sanitarian, or sanitarian-in-training employed by or contracted with the local board of health having jurisdiction, prior to issuance or renewal of its license or on a regular annual inspection.

(8) The food manufacturing establishment must sample and have analyzed its manufactured ice products, and the waters from which the ice is made, at least once a month for compliance with the maximum microbiological contaminant levels contained in ARM 17.38.207, and send the results to the department. The food manufacturing establishment is also required to comply with the bacteriological quality sampling provisions of ARM 17.38.215 (3) through (7) for transient non-community water systems. The department may increase the required sampling frequency based upon sampling results or other conditions which indicate an increased risk to the health of the users of the product. The department may decrease the required sampling frequency to quarterly or biannually based on a showing that the source consistently does not contain the contaminant, is either a community water system or a groundwater source not under direct influence of surface water, and that the samples consistently meet the required sanitary standards, rendering the source and operation generally not vulnerable to microbiological contamination.

(9) The delivery of ice to the customer must be done under sanitary conditions. Ice must be packaged in durable freezable containers labeled in conformance with the labeling requirements as described in (6) above. Boxes or containers intended for non-food use or for use in packaging another food are not acceptable transport containers. All boxes, containers, cases or contact surfaces within bins or transport vehicles must be constructed of food grade materials.

(10) Natural or manufactured ice that does not conform to standards set forth in this rule must be conspicuously identified or labeled as unsafe or inedible and may not be sold or distributed for human consumption. Such ice may be used for cooling or refrigeration purposes only if such use does not permit it to come in direct contact with food or drink meant for human consumption. If such ice is sold or distributed for refrigeration purposes, the seller or distributor must notify the buyer or consumer that it is not safe for human consumption.

(11) The department hereby adopts by reference ARM 37.110.301 et seq., setting standards for food manufacturing establishments; ARM 17.38.201, et seq., setting standards for public water supply systems; 21 CFR 110, setting standards for packing, manufacturing, or holding human food; and 21 CFR 101, setting food labeling standards. Copies of these rules may be obtained, upon payment of copying costs, from the Department of Public Health and Human Services, Food and Consumer Safety Section, 1400 Broadway, P.O. Box 202951, Helena, Montana 59620-2951. (History: Sec. 50-31-104, 50-31-201 and 50-50-103, MCA; IMP, Sec. 50-31-104, 50-31-201 and 50-50-103, MCA; NEW, 1994 MAR p. 2832, Eff. 10/28/94; TRANS, from DHES, 2001 MAR p. 2423.)

Rules 03 and 04 reserved

37.110.805 COMMON CARRIERS (1) Water and ice provided by common carriers for drinking or culinary purposes in railway trains, buses, or other public transportation conveyances and in all railway stations in Montana must be taken from supplies which conform to standards for drinking water contained in 40 CFR 141 and 40 CFR 142.

(2) The department hereby adopts by reference 40 CFR 141, setting maximum contaminant levels and other standards for drinking water, and 40 CFR 142, establishing procedures for implementing and enforcing drinking water standards. Copies of these rules may be obtained, upon payment of copying costs, from the Department of Public Health and Human Services, Food and Consumer Safety Section, 1400 Broadway, P.O. Box 202951, Helena, Montana 59620-2951. (History: Sec. 50-50-103, MCA; IMP, Sec. 50-50-103, MCA; NEW, 1994 MAR p. 2832, Eff. 10/28/94; TRANS, from DHES, 2001 MAR p. 2423.)

Rules 06 through 09 reserved

37.110.810 MINIMUM PERFORMANCE REQUIREMENTS FOR LOCAL HEALTH AUTHORITIES (1) To qualify for reimbursement under 50-50-305, MCA, for regulation of sources of drinking water and ice, a local board of health must either enter into a written, signed cooperative agreement with the department that establishes the duties and responsibilities of the local board of health and the department consistent with this subchapter, or ensure that the following are done by the local health officer, sanitarian, or sanitarian-in-training:

(a) Ensure that, at least once per year, each plant or establishment within the jurisdiction of the local board of health where water is prepared for sale in bottles or other containers or artificial ice is manufactured, and the sources of all such water, are inspected, either by the foregoing individuals or by another government agency and, at the same time, that a sample of the water is submitted to a DEQ-approved laboratory for analysis for contaminants.

(b) Submit quarterly inspection reports to the department within 10 days following the close of each quarter of the fiscal year (1st quarter--September 30; 2nd quarter--December 31; 3rd quarter--March 31; 4th quarter--June 30) on forms approved by the department.

(c) Retain for 5 years all documentation of enforcement of this subchapter, including but not limited to inspection reports, consumer complaints, illness investigations, plans of correction, and enforcement actions, and, upon request, submit copies of the documentation to the department or otherwise make it available to the department.

(2) A failure by the local board of health to meet all of its responsibilities under the cooperative agreement or under (1)(a) through (d) above shall result in the withholding of funds from the local board reimbursement fund in an amount to be determined by the department. (History: Sec. 50-50-305, MCA; IMP, Sec. 50-50-305, MCA; NEW, 1994 MAR p. 2941, Eff. 11/11/94; AMD, 1995 MAR p. 26, Eff. 11/11/94; TRANS, from DHES, 2001 MAR p. 2423.)